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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,494	04/18/2000	Frank Meulewaeter	021565-075	2755

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/551,494

Applicant(s)

MEULEWAETER ET AL.

Examiner

Janet Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32,34,38-43,45 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39-41 and 50-52 is/are allowed.
- 6) ☒ Claim(s) 32,34,38,42,43,45 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Claims 1-31, 33, 35-37, 44, 46-48, 53-54 were cancelled by Applicants without prejudice or disclaimer.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 32, 34, 38, 42-43, 45, and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzmaurice et al., and Masuta et al. in view of Grierson et al., for the reasons of record set forth in the Official Action mailed 12-14-2001.

Applicant's arguments filed 5-14-2002 have been fully considered but are not persuasive. Applicants traverse the instant rejection on the grounds that the combined teachings of Fitzmaurice et al., and Masuta et al., in view of Grierson et al. do not motivate the person skilled in the art to modify the vectors of Fitzmaurice et al. into the vectors of the present invention, since neither reference teach nor suggest that silencing of endogenous genes can be obtained by satellite-virus derived RNA vectors comprising sense inhibitory RNA. Furthermore, Applicants argue that there was no reasonable expectation that satellite RNA viruses, such as STMV or STNV, modified to comprise sense RNA, could be successfully used for silencing of nuclear encoded (endogenous) plant genes. Additionally, Applicants argue that Masuta et al. relates to vectors derived from "satellite RNAs," and not to "satellite viruses."

However, contrary to Applicant's assertions, as stated in the prior Office Action, Grierson et al. teach constructs and methods for enhancing the inhibition of a target gene within an organism comprising inserting into the gene silencing vector an inverted repeat sequence of all or part of a polynucleotide region within the vector. The inverted repeat sequence may be a

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synthetic polynucleotide sequence or comprise a modified natural polynucleotide sequence. In a preferred embodiment of Grierson et al., gene silencing vectors are disclosed, which comprise 5'-UTR inverted repeat sequences (antisense to naturally occurring 5'-UTR) positioned upstream of the coding sequence (i. e. sense sequence; see page 5, lines 1-30). The constructs of Grierson et al. comprise both an antisense and a sense portion, wherein upon transcription of the coding region of said construct yields inhibitory RNA which comprises both a sense and an antisense region (see also Grierson et al. page 4, lines 18-21).

In regards to Applicant's arguments that the teachings of Masuta et al. do not disclose the use of satellite viruses, contrary to Applicant's assertions, it is noted that the instant claims recite wherein the viral RNA vector is derived from a satellite RNA virus. The teachings of Masuta et al. clearly relates to the use of a vector comprising satellite RNA of a plant virus (see col. 2, lines 9-18), particularly wherein the satellite RNA may be derived from a satellite virus, including both STNV and STMV, or wherein the satellite RNA may be contained within helper virus particles (see lines 18-28).

Moreover, Applicants argue that prior to the filing of the present invention the use of satellite vectors as silencing vectors was generally doubted by persons skilled in the art, as such vectors were believed to be unstable and as satellite viruses were known to have a high mutation rate. In regards to Applicant's allegation regarding unpredictability associated with the use of satellite vectors as silencing vectors, Applicants have not provided any credible evidence to substantiate their allegation of non-enablement with regards to the expectation of success for modifying Fitzmaurice et al. and Masuta et al. with the teachings of Grierson into the vectors of the present invention. Additionally, contrary to Applicant's assertions, the STMV-based

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transformation and expression system of Fitzmaurice et al. may be applied to a broad range of plant systems, including herbaceous plants such as solanaceous plants, e.g. tobacco (member of *Nicotiana* spp.) , tomato, etc. (see page 15, lines 26-30). Therefore, absent evidence to the contrary, the modified constructs of Fitzmaurice et al. in view of Grierson et al. would be expected to have the same properties as Applicant's constructs, since Applicant's constructs are not unobviously different from the prior art constructs.

Furthermore, although Applicants have cancelled claims reciting inverted repeats, it remains that the inverted repeat sequences of Grierson et al. still read on an antisense region, therefore the constructs of the present invention comprising both a sense and antisense region, are still encompassed by the teachings of Grierson et al. As stated in the prior Office Action, Grierson et al. "have found that the inhibitory effect of a gene silencing vector can be enhanced by creating in the vector an inverted repeat (i.e. antisense region) of a part of the sequence of the vector (page 4, lines 24-26). Therefore, one of ordinary skill in the art would have been motivated to modify the teachings of Fitzmaurice et al., and Masuta et al. by incorporating one or more inverted repeats (i.e. antisense regions) and/or sense regions into these constructs since the modified constructs of Grierson et al., comprising both a sense and an antisense region are clearly expected to have enhanced properties in comparison to unmodified constructs.

### ***Conclusion***

4. Claims 39-41 and 50-52 are free of the prior art for the reasons of record set forth in the Official Action mailed 12-14-2001.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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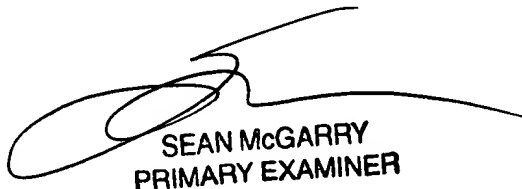
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps  
Examiner  
Art Unit 1635  
*JLE*  
July 23, 2002

  
SEAN McGARRY  
PRIMARY EXAMINER